

Appl. No. 10/018,617  
Amdt. dated  
Reply to Office Action of May 7, 2003

### REMARKS

Applicants filed a Preliminary Amendment adding new claims 52-93 on May 13, 2003. Given that the outstanding Office Action was mailed on May 7, 2003 and states claims 1-51 are pending, it appears that the two papers crossed in the mail. Therefore, please note that the Listing of the Claims above includes claims 52-93 as submitted in the Preliminary Amendment, and other remarks contained herein will refer to claims 52-93 as well.

Claims 1-93 (claims 1-51 as originally filed and claims 52-93 as filed on May 13, 2003 in a Preliminary Amendment) were pending in the above-identified application prior to entry of this Amendment. In this Amendment, claims 1, 2, 3, 7, 11, 14, 17, 21, 42, 43, 48, and 49 have been cancelled. Applicants reserve the right to pursue these cancelled claims in future continuation or divisional applications. Claims 5, 6, 10, 12, 16, 18, 20, 22, 23, 24, 26, 27, 38, 46, 47, 50, and 51 have been amended. Accordingly, after entry of this Amendment, claims 4-6, 8-10, 12, 13, 15, 16, 18-20, 22-41, 44-47, and 50-93 are pending in this case. The changes to the claims do not constitute the addition of new matter and full support for the changes may be found in the specification and claims as originally filed. Specifically, support for the amendments to claim 38 may be found on page 6, line 25 to page 7, line 2 of the specification. Support for the amendments to claim 16 may be found on page 25, line 3 of the specification.

The Examiner has acknowledged that the International Search Report for PCT IB 01/00026 was submitted along with the cited references of such report and that these references have been considered in the instant Office Action (i.e. Paper No. 4). However, the Examiner indicates in Paper No. 4, that no Information Disclosure Statement (IDS) was submitted. Applicants respectfully submit that an IDS was submitted with respect to this pending application. A copy of the previously submitted Certificate of Mailing, transmittal, Form 1449 and return postcard indicating receipt of the IDS is included herein as proof of submission. Pursuant to the provisions of M.P.E.P. 609, it is respectfully requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

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**Rejection Under 35 U.S.C. §101**

The examiner has rejected claims 46 and 47 under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter.

As suggested by the Examiner, claims 46 and 47 have been amended to read as method claims.

In view of these amendments and remarks, withdrawal of the rejections under 35 U.S.C. §102(a) is respectfully requested.

**Rejection Under 35 U.S.C. §112, Second Paragraph**

The examiner has rejected claims 43 and 48 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

The cancellation of claims 43 and 48 renders this rejection moot.

In view of these amendments and remarks, withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

**Rejection Under 35 U.S.C. §102(b) or, in the Alternative, Under 35 U.S.C. §103**

The examiner has rejected claims 1-45 and 49-51 under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Bisgaier et al. (WO 99/03704). This rejection is respectfully traversed.

Currently pending claims 5-93 relate to crystalline forms, and methods for their use, of various salts, solvates, and hydrates of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid. WO 99/30704 does not disclose each and every element of the claimed invention. Nowhere however, does WO 99/30704 disclose crystalline forms of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid its salts or hydrates. The claimed invention is novel in light of WO 99/30704 given the absence of this limitation that the compound be crystalline.

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Additionally, WO 99/30704 does not teach or suggest one to make a *crystalline* form of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid its salts or hydrates. Simply making a compound does not result in the production of a crystalline form of that compound. Many compounds are only amorphous and simply do not exist in a crystalline form. Many materials that are apparently solid, such as glasses, lack a definite crystal structure and are thus not crystalline. Thus, based on WO 99/30704, the skilled person would neither have even known that crystalline forms of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid its salts or hydrates exist or could be produced as disclosed in the present application, nor that they existed or could be produced at all.

Furthermore, the crystalline compounds of the present invention, as stated on page 14, lines 10-23, is of a higher bulk density which is consistent upon scale up and is less electrostatic than the amorphous form. These characteristics of the crystalline compounds which greatly improves the handling characteristics of the bulk product in large scale production and simplifies manufacturing of pharmaceutical dosage forms. WO 99/30704 simply does not teach or suggest any of these advantages that *crystalline* forms of 6-(5-carboxy-5-methyl-hexyloxy)-2,2-dimethylhexanoic acid its salts or hydrates provide.

Crystallinity is a distinct characteristic that may vary even for a single compound, as is the present case. Crystals have characteristic shapes and cleavage planes due to the arrangement of their atoms, ions or molecules, which form a definite pattern called a lattice. Crystals also vary in terms of their index of refraction, magnetic and electrical properties, and whether it is anisotropic or isotropic.

In view of these amendments and remarks, withdrawal of the rejection under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) is respectfully requested.

The above discussion and corresponding Amendments are based on section 112 issues and are not made to overcome art-based rejections. Accordingly, such discussion and corresponding Amendments should not be construed in a limiting manner.

It is respectfully submitted that the claims have been put in condition for allowance. Notification to this affect is earnestly solicited. The Examiner is encouraged to contact the

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Applicants' undersigned attorney to discuss this matter if any questions should arise upon further examination of the pending claims.

Respectfully submitted,

August 6, 2003  
Date

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